

CHAPTER- 5

Materials and Methods

5.0 MATERIALS AND METHODS

5.1 Design:

Randomized Controlled trial with parallel groups.

5.2 Subjects

Obese adult male and living in urban area, n=80

5.3 Source and Setting

The subjects were screened from the general population of an urban setting of North and East Mumbai locality and open to varied socio demographic sections of the community.

5.4 Selection Criteria

Recruitment of subjects was based on the selection criteria listed below.

Table- 5 Inclusion Exclusion criteria

Inclusion Criteria	Exclusion Criteria
BMI from 23 to 35 Kg/m ² (Initially planned to separate BMI 23 to 25 as overweight and above 25 Kg/m ² as obese. However all enrolled were obese.)	BMI below 23 Kg/m ² and BMI above 35 Kg/m ² Female
Male	Physically handicapped
Age 18 years to 60 years	Those with 6 months regular yoga practice
General Health	Cannot read and write English
Capability to perform simple yoga practices	Surgeries in the past 6 months
Minimum 10 th Standard Passed	Medically restricted from physical activity as listed below

List of conditions for excluded as a part of medically restricted activity:-

Table- 6 Medically restricted activity

Sl No	Condition (Person having)	Remarks
1	Any surgery done during past six months	
2	Any contagious disease /infections Any severe condition of Non communicable diseases	
3	Any Pain in any part of body	
4	Any swelling /bleeding in the body parts	
5	Fever	
6	Any severe medical conditions like Asthma, Cancer, Heart diseases, Hernia, Hydrocele, Spinal problems, severe back/ neck / shoulder problems, Spondylitis, Lumbago, Ulcer, Appendicitis, Colitis, High Blood pressure or any mental illnesses	
7	Any contra indicated physical or mental condition for the respective yoga practice in the intervention	As per Yoga module
8	Any abnormal health condition	

5.5 Sample Size

This is based on one earlier study on obesity (Dhananjai, Sadashiv, Tiwari, Dutt, & Kumar, 2013). The effect size for 4 primary outcome variables was calculated i.e. Weight= 0.84, BMI= 0.64, Waist Circumference (WC) = 1.11 & Hip Circumference (HC) = 0.56 and decided to use the smallest effect size to calculate the sample size i.e. HC=0.56 which projected a sample size of 29. An attrition of 20% was assumed and sample size (n=35) was calculated using Cohen's formula (alpha of 0.05, powered at 0.90) using G*power program (Faul, Erdfelder, Lang, & Buchner, 2007). Control group also had an equal sample size of n=35.

5.6 Minimization

Minimization of following co factors was done to ensure the excellent balance between groups.

- a) Age groups of 18 to 40 years and 41 years and above
- b) Groups of Education level (up to graduates, and Post graduates plus above)
- c) Employed and Non employed

Studies say that rather than stratified randomization with several variables, blocking and stratification is better to have balance between groups, in size as well in characteristics of subjects. Hence each allocation will minimize the unbalance between groups (Altman & Bland, 2005).

Studies concluded that minimization is very effective allocation method in randomized controlled trials (Scott, McPherson, Ramsay, & Campbell, 2002). The minimization was done with an open source software MinimPy (Altman & Bland, 2005).

5.7 Ethical Clearance and Consent

The approval of institutional ethical committee was obtained. Further, the informed consent was administered prior to screening and recruitment.

5.8 Screening

The screening was carried out based on BMI values as per the inclusion criteria. Further the all baseline parameters including the psychological profile were assessed as per inclusion criteria, before the randomization.

The participants were healthy except the condition of obesity. General health questionnaire GHQ-12 was administered to all subjects and found that they were healthy. Further the medically restricted conditions were part of exclusion criteria. Medical condition/case history was self-reported by the subjects. The trial profile is given in Figure- 3.

Figure- 3 Trial profile

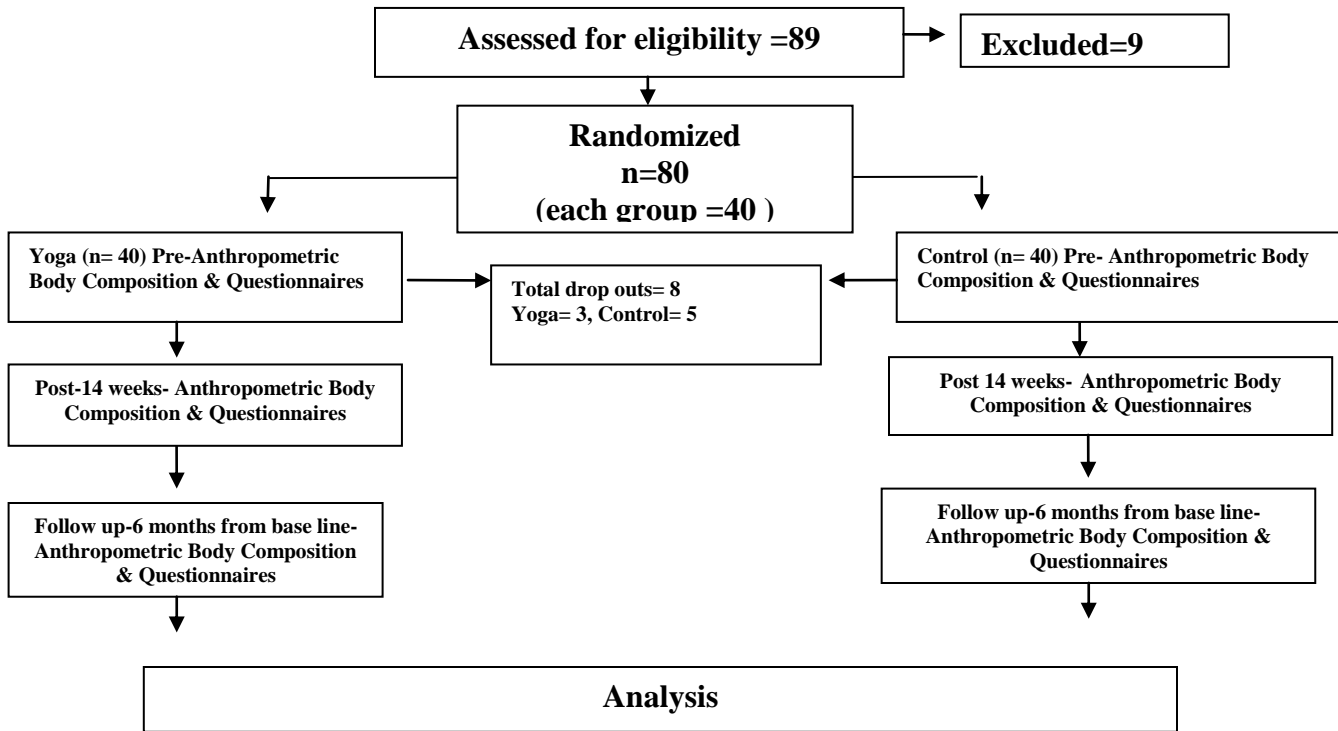


Table- 7 IAYT COMPONENTS

THE FIVE PART DAILY (FIVE DAYS IN A WEEK) IAYT INTERVENTION		
Sl. No.	Yoga Practice	Duration (minutes)
1	Lecture & Counselling	10
2a	Warm Up	10
2b	<i>Surya Namaskāra</i>	10
3	<i>Asana</i>	30
4	<i>Praṇāyāma</i>	15
5	Meditation	15
	Total duration	90

5.9 Randomisation

Subjects were randomly allocated into the yoga and control group. This was done using computer generated random numbers (using the open source software MinimPy).

5.10 Blinding and confidentiality

Except for the persons directly involved in recruitment and intervention, all others were blinded, to the grouping of the subjects. It was achieved through giving each individual an alphanumeric code and removing personal identifiers of name and group. The blinding was not possible among the groups and subjects were informed about their group allocation after randomization.

5.11 Assessments

Anthropometric parameters

Weight:

Weight was measured using the research grade electronic weighing scale (InBody R20 instrument) and the same scale was used for all time points. Weight was measured in kilograms.

Height:

A measuring tape placed vertically against the wall corresponding to the height and the subjects stood erect against the wall. A ruler placed parallel to the floor on top of the subjects head would indicate height on the tape. This was noted in centimetres.

Body Mass Index:

BMI was calculated from weight and height. Though inclusion criteria were BMI from 2 to 35 all the subjects were more than 25 kg/m².

Waist Hip Ratio:

Waist circumference was measured at the midway between the lowest rib margin and iliac crest, and hip circumferences were measured at the widest trochanters.

A' Body Shape:

The 'A' Body Shape Index (ABSI) was calculated using height, mass and waist circumference (Dabhadkar, Deshmukh, Bellam, & Tuliani, 2013; Krakauer & Krakauer, 2012; Romero-Corral et al., 2008)

Skin Fold Thickness:

The standard skin fold thickness calliper was used to measure this data (Jensky-Squires et al., 2008; West, Manchester, Wright, Lawlor, & Waiblinger, 2011). The assessments were done at standardized four locations of Biceps, Triceps, Suprailiac and Sub scapular sites (Jensky-Squires et al., 2008).

Body Composition Parameters

Body composition was assessed by BIA method (Bioelectric Impedance Analysis) (Kyle et al., 2004). The InBody R20 Serial number PA 904F1D1 of Bio space Co Ltd UK was used for all the three time measurements.

Following are the parameters:

Body Fat Mass

Percentage Body Fat

Skeletal Muscle Mass

BMR

Waist Hip Ratio

Total Body Water

Fat Free Mass

Segmental Muscle Mass of five locations (both legs, both arms and trunk)

Segmental Fat Mass of five locations

Psychological Parameters

Following psychological parameters were measured. These were validated and reliable psychometric tools. Below are details of the psychometric instruments used for each of the psychological variables (Total number of questions/sub questions answered by subjects were 85). Food/ exercise log was format was given and asked to the subjects to follow.

Table- 8 Psychological parameters

Sl No	Variable Name	Instrument	Description
1	Perceived Stress Scale	PSS	The PSS is a 10 question instrument with established psychometric properties (Lee, 2012).
2	Physical activity	IPAQ	This tool evaluates self-reported measures of physical activity and has been validated for Asian populations (Nang et al., 2011).

3	Patient Health Questionnaire	PHQ	This questionnaire meets the criteria for good diagnostic accuracy (Nang et al., 2011; Zuithoff et al., 2010).
4	Acceptance and Action Questionnaire for Weight-Related Difficulties	AAQ-W	The AAQW (Lillis & Hayes, 2008) has internal consistency (alpha= 0.88) and correlated with other measures.
5	Mindful Attention Awareness Scale	MAAS	The MAAS is used in research of Psychological well-being (Carlson & Brown, 2005; MacKillop & Anderson, 2007). It has validity evidence (Cordon & Finney, 2008).
6	Sleep Quality	PSQI	This is used in similar applications (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989; Kiecolt-glaser et al., 2012).
7	BREQ-2 (Behavioural Regulation in Exercise Questionnaire).	BREQ-2	This is validated and used in research studies (Ingledeu & Markland, 2008; Markland & Ingledeu, 2007; Moustaka, Vlachopoulos, Vazou, Kaperoni, & Markland, 2010).

5.12 Data extraction/ Procedure

All the assessments including body composition parameters were assessed in the morning with overnight fasting. For the body composition assessments, the instrument used was InBody R20 serial number PA 904F1D1 of M/s Bio space Co Ltd. from UK.

All metallic items were removed from pockets and the subjects were asked to stand straight and still on the foot pad with light clothing. The foot was placed in the foot pad as per the shape of the electrode guide. First the body weight was recorded and then handle was taken and given to the

subject. Subjects held the handle in stand still position. The readings were directly transferred to the connected computer.

All the psychological parameters were taken in single sitting before the Anthropometric and body composition measurements.

5.13 Data analysis

The data was analysed using SPSS software 21 version. Normality test was carried out using Shapiro-wilks test. The Paired sample t test was carried out for Pre Post, Pre Followup and for Post Followup values, for both the groups on all the variables which were found normally distributed. For not normally distributed parameters, Wilcoxon signed ranks test was carried out. The between groups analysis was performed using independent sample t test for the Pre as well as for Post values of the groups.

A correlation test was carried out to find the relative improvements from Pre to Post readings, and from Pre to Followup readings, among the variables. A value of $p < 0.05$ was considered statistically significant.